

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



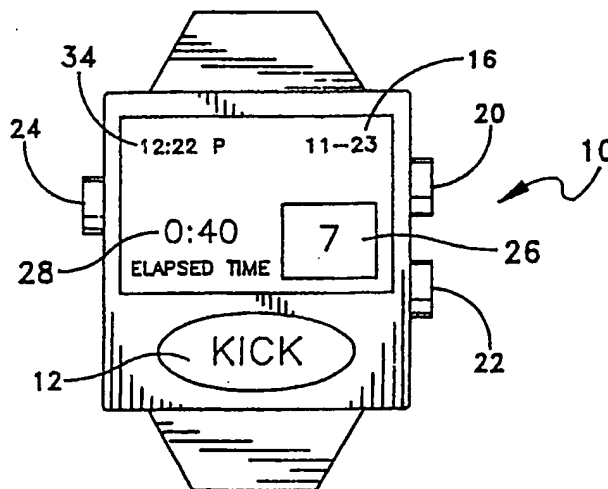
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : G04F 10/00, G04G 1/00	A1	(11) International Publication Number: WO 99/52020 (43) International Publication Date: 14 October 1999 (14.10.99)
(21) International Application Number: PCT/US99/07426 (22) International Filing Date: 2 April 1999 (02.04.99) (30) Priority Data: 60/080,713 3 April 1998 (03.04.98) US (71)(72) Applicant and Inventor: ROSENBLATT, Peter, L. [US/US]; 25 Bruce Lane, Newton, MA 02458 (US). (74) Agents: McLANE, Jodi-Ann et al.; Salter & Michaelson, 321 South Main Street, Providence, RI 02903-7128 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: METHOD AND DEVICE FOR COUNTING AND RECORDING FETAL MOVEMENT

(57) Abstract

An electronic device that registers each perceived fetal movement input by a pregnant woman over a predetermined amount of time depending upon the kick-count protocol utilized is provided. The device is programmed to compare the number of movements input to an index for the particular protocol, in order to determine if an adequate number of movements have been input, and informs the user by a visual and/or auditory cue if an adequate number of movements have not been input. The device may then signal to the patient to contact her obstetrical provider for an evaluation of fetal well-being. In one embodiment, the device is preferably programmable to be utilized with any of the aforementioned kick-count protocols, depending upon the obstetrical providers preference.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

1 **METHOD AND DEVICE FOR COUNTING**
2 **AND RECORDING FETAL MOVEMENT**

3
4 **Description**

5
6 1. **Cross Reference to Related Applications**

7 This application claims priority under 35 U.S.C. §119(e) to commonly-owned,
8 co-pending U.S. Provisional Patent Application Serial No. 60/080,713, entitled
9 DEVICE FOR COUNTING AND RECORDING FETAL MOVEMENT, filed
10 April 3, 1998, by Peter L. Rosenblatt, which is incorporated herein by reference in its
11 entirety.

12
13 2. **Technical Field**

14 The invention relates generally to a device and method for counting and
15 recording fetal movement, and more particularly to a device which automatically
16 prompts a pregnant woman to count fetal movement, registers each movement
17 perceived by the mother over a predetermined amount of time and notifies the
18 pregnant woman if an adequate number of movements have been registered during the
19 predetermined amount of time.

20
21 3. **Background of Related Art**

22 It is well established that maternal assessment of fetal activity, or so called
23 "kick-count" protocols, are a simple, effective and reliable method of monitoring fetal
24 well-being in high-risk pregnancies. (As used herein the term "kick-count" protocol
25 refers to any protocol for maternal assessment of fetal activity or movement). More
26 recently, it has been demonstrated that these kick-count protocols can lower
27 antepartum stillbirth rates in low-risk pregnancies as well.

28 Studies using real-time ultrasonography have shown that in the third trimester
29 the human fetus spends approximately ten percent of its time making gross body

-2-

1 movements, and that the average fetus moves thirty times each hour. However, most
2 women are able to perceive only 70 to 80 percent of such gross body movements.
3 Factors that may reduce maternal perception of gross fetal movements include
4 maternal obesity, anterior placentation, and both polyhydramnios as well as
5 oligohydramnios. In addition, several medications, including narcotics and
6 barbiturates, may reduce fetal activity. Contrary to popular belief, fetal activity does
7 not increase following meals, but rather is enhanced by maternal hypoglycemia. Fetal
8 activity tends to peak in the late evening, between 9:00 p.m. and 1:00 a.m., which
9 correlates with declining maternal glucose levels. Fetal movement appears to be
10 strongly correlated with fetal oxygenation as well. Using a sheep model, Natale et al.
11 demonstrated a significant decline in fetal activity associated with minor reductions
12 in fetal P_{O_2} . The ability of kick counting protocols to predict fetal compromise is
13 based upon this phenomenon of decreased fetal activity resulting from hypoxemia.

14 Maternal monitoring of fetal movements in the third trimester of pregnancy has
15 been advocated for all pregnancies. Although there is no single accepted protocol,
16 several methods for monitoring fetal movements have been described in literature.
17 One of the most popular methods, described by Pearson and Weaver, involves the use
18 of the Cardiff Count to Ten chart. The patient is asked to count fetal movements each
19 day and record how much time it takes to perceive ten movements. In this study,
20 patients were asked to contact their obstetricians if 12 hours had passed before ten
21 movements were perceived, or if the time to reach the tenth movement increased each
22 day. Sadovsky et al. described an alternate method whereby patients count fetal
23 movement for 30 to 60 minutes, two or three times each day. If less than ten
24 movements are counted in 12 hours (the "movement alarm signal"), the patient is
25 instructed to contact her physician for further fetal evaluation. In another method,
26 Rayburn et al. recommended counting fetal movements for 60 minutes each day and
27 suggested that less than three movements an hour for two consecutive days may
28 indicate fetal distress. A study conducted by Sadovsky et al. which evaluated the

1 various techniques used for kick counts found the "movement alarm signal" and the
2 "Count to Ten" methods to be the most valuable.

3 More recently, an alternative protocol for kick counting was described by
4 Moore and Piacquadio to accommodate the "busy life-style of the contemporary
5 pregnant woman." Starting at 28 weeks gestation, women were asked to record the
6 time required to appreciate ten fetal movements (defined as "any discrete kick, flutter,
7 swish, or roll"), while lying on their left side. Women were instructed to perform this
8 kick counting on a daily basis, but exclusively in the evening hours, between about
9 7 p.m. - 11 p.m., when fetal activity is most pronounced. If two hours elapsed before
10 noting the ten movements, women were instructed to go to labor and delivery for an
11 evaluation. During their prospective study, a total of 4,383 deliveries occurred (2,519
12 during a control period without formal kick counting and 1,864 during the study
13 period with the new protocol). They found that this simplified protocol resulted in a
14 significant drop in fetal mortality from 8.7 to 2.1 per 1,000 deliveries. Among those
15 women who presented with decreased fetal movement, interventions for fetal
16 compromise resulted in a reduction in fetal mortality from 44 to 10 per 1,000. In this
17 study, the mean time to perceive ten fetal movements was only 20.9 + 18.1 min (mean
18 + Standard Deviation). Furthermore, after 90 minutes, 99.5% of women perceived ten
19 movements. Therefore, using a cutoff time of 2 hours, only 1 in 500 women were
20 found to ever exceed this upper time limit and require additional testing. As the drop
21 in fetal mortality in this study confirms, this 2 hour cutoff time appropriately selects
22 those patients at significant risk. Instructing women in fetal kick counting did result
23 in an overall increase in antenatal testing (e.g. nonstress test, contraction stress test)
24 of 13%, although the drastic reduction in fetal mortality certainly justifies this modest
25 increase in antenatal testing.

26 The efficacy of "kick count" protocols in decreasing antenatal stillbirth has
27 been well documented in a number of large clinical trials. In addition to Moore and
28 Piacquadio, Nedlam conducted a prospective, randomized study in which 1,562
29 women at 32 weeks gestation were asked to count fetal activity 3 times a week for 2

-4-

1 hours after a meal. Patients who noted less than 3 movements each hour were further
2 evaluated with ultrasound and nonstress testing. Only one stillbirth occurred in the
3 monitored group, compared with ten stillbirths in the control group of 1,549 women.
4 This study clearly demonstrates the sensitivity of this kick counting technique in
5 selecting those patients at risk for fetal demise. Of the 4% of women in the monitored
6 group who reported decreased movement, nearly 25% were confirmed to have fetal
7 distress based on further testing. These investigators attributed the prevention of 14
8 fetal deaths in the monitored group to the use of this simple technique. Rayburn
9 reported that when using his method (described above) of the 5% of the women who
10 reported decreased fetal activity, the incidence of stillbirth was 60 times higher, and
11 the incidence of severe intrauterine growth retardation and low Apgar scores were 10
12 times higher than for women who reported normal fetal activity.

13 In view of the foregoing, it is apparent that accurately and consistently
14 recording fetal activity in the third trimester can forewarn of fetal distress and help
15 prevent antenatal still births. Of course, for any "kick count" protocol to be effective,
16 the pregnant woman must accurately follow the prescribed protocol, report any
17 deviation to her obstetrician, and follow-up with further testing, such as a nonstress
18 test. However, compliance rates for fetal kick counting have been reported to range
19 from 50% to 83%, depending upon several factors, such as the study population and
20 the complexity and length of the kick counting protocol. Clark and Britton described
21 factors which contribute to patient noncompliance with the Cardiff Count to Ten
22 protocol. They reported that 27% of the patients filled out their charts less than 50%
23 of the time and that 65% of the subjects who experienced movement alarm signals did
24 not notify their care providers. In suggesting possible explanations for this poor
25 compliance, they noted that more than a third of patients reported that their care
26 providers never asked about their charts at subsequent prenatal visits. In addition,
27 82% of patients were unclear on how to record their interval times when not starting
28 the counting at 9 a.m. Another 23% of patients did not know how to contact their care
29 provider if they had a movement alarm signal. Additionally, difficulty in marking the

-5-

1 chart was reported in 16% of the subjects. These authors conclude that strategies for
2 improving patient compliance need to be developed in order to make fetal kick
3 counting more beneficial.

4 It is therefore an object of the present invention to provide a device for
5 simplifying administration and compliance with any of the various kick-count
6 protocols.

7 It is another object of the present invention to provide a device which
8 automatically prompts a pregnant woman to count fetal movement and notifies the
9 pregnant woman if an adequate number of movements have, or have not been counted
10 during a predetermined amount of time.

11 It is a further object of the present invention to provide a method of fetal
12 monitoring which records fetal movement data during a predetermined time interval,
13 compares the data to a target index of fetal movement and notifies the patient and/or
14 care provider of the results.

15 Summary

16 In accordance with the present invention, there is provided an electronic device
17 that registers or records each perceived fetal movement input by a pregnant woman
18 over a predetermined amount of time (depending upon the kick-count protocol
19 utilized). The device is programmed to compare the number of movements input to
20 an index for the particular protocol, in order to determine if an adequate number of
21 movements have been input, and informs the user by a visual and/or auditory cue if
22 an adequate number of movements have not been input. The device may then signal
23 to the patient to contact her obstetrical provider for an evaluation of fetal well-being.
24 In one embodiment, the device is preferably programmable to be utilized with any of
25 the aforementioned kick-count protocols, depending upon the obstetrical providers
26 preference. The device may also be programmed to inform the user if an adequate
27 number of movements have been input, if the fetal movement session has been
28

-6-

1 interrupted, if no fetal movements have been input for a predetermined number of
2 days, and to display the results of current and previous sessions.

3 In one embodiment, the device may be programmable so that the patient can
4 input her due date, and may then also function as a counter to indicate how many days
5 remaining until the due date, or how many days have elapsed since the beginning of
6 the pregnancy. If the due date is programmed into the device, then the device may
7 also include information or prompts to the patient based upon the gestational week or
8 date. For example, the device may provide information concerning the fetus, such as
9 the development of sexual organs, and/or the device may provide reminders to the
10 patient such as to practice breathing techniques or Kegel exercises. The device may
11 also take any number of forms, including but not limited to a watch, necklace,
12 electronic personal organizer and may be carried in a woman's pocket, clipped on to
13 clothing (like a beeper) or worn on the woman's clothing or body. In a preferred
14 embodiment, when not in use as a kick counter, the unit may be used as a conventional
15 watch or clock.

16 In use, the care provider chooses which of the programmed protocols he or she
17 wishes the patient to utilize during the third trimester of pregnancy. Once the protocol
18 is selected, the device automatically prompts the patient to begin counting fetal
19 movement at a certain time of day, depending upon the protocol. The user then inputs
20 perceived movements into the device during the predetermined time period for the
21 session, which is again dependent upon the protocol. The device is programmed to
22 count the inputted movements and compare the number of movements to an index for
23 the particular protocol. The device then automatically notifies the user if the session
24 has not been successfully completed (i.e. the number of movements registered
25 compared to the index is not correct). The device may additionally notify the user if
26 the session has been successfully completed (i.e. the number of movements registered
27 compared to the index is correct). The patient may also interrupt the session, if
28 necessary, in which case the device may record the interruption. Upon completion of

-7-

1 a session the device may revert back to a conventional watch or clock, and/or may
2 display the results of the completed session until the next session is begun.

4 Brief Description of the Drawings

5 It should be understood that the drawings are provided for the purpose of
6 illustration only and are not intended to define the limits of the invention. The
7 foregoing and other objects and advantages of the embodiments described herein will
8 become apparent with reference to the following detailed description when taken in
9 conjunction with the accompanying drawings in which:

10 Fig. 1 is a front view of a device in accordance with one embodiment of the
11 present invention in a "ready" mode prepared to receive input from the patient for
12 counting fetal movement and configured to be worn as a wrist watch;

13 Fig. 2 is a front view showing the device of Fig. 1 in an "in-use" mode during
14 counting of fetal movement;

15 Fig. 3 is a front view showing the device of Fig. 1 in an "alert" mode
16 instructing the user to contact a physician;

17 Fig. 4 is a front view showing the device of Fig. 1 in a "result" mode
18 displaying the results to the user after receiving input and comparing it to the
19 appropriate index for a given kick-count protocol;

20 Fig. 5 is a front view showing the device of Fig. 1 also in a "result" mode and
21 displaying to the user the number of days past the patient's due date;

22 Fig. 6 is a front view showing the device of Fig. 1 in an "alarm" mode
23 notifying the user that the number of kicks recorded did not meet the protocol standard
24 and to notify her physician;

25 Fig. 7 is a front view showing the device of Fig. 1 in a "pass" mode notifying
26 the user that the number of kicks recorded did meet the protocol standard;

27 Fig. 8 is a front view showing the device of Fig. 1 in an "non-use" mode in
28 which the device displays no results as the patient has not entered any results for the
29 day;

Fig. 11 is a schematic block diagram of the device of Fig. 1;

Fig. 12B is a front view of the device of Fig. 12A in the “in-use” mode; and

Detailed Description of the Illustrative Embodiments

A device 10 for automatically prompting a pregnant woman to input or count perceived fetal movements, and which registers each movement perceived by the woman over a predetermined amount of time is illustrated in Fig. 1. The device preferably includes an input member 12 for actuation by the user to input fetal movements as they occur during a given session, a timer 14 for timing the elapsed time since the beginning of the session, a processor for comparing the number of fetal movements input relative to an index for a given "kick-count" protocol and an indicator or display 16 for conveying information to the user. The input member 12 may be in the form of a button 12 which is used to start the session and which, when depressed by the user, inputs the fetal movements which may then be registered by a counter. The counter may be any conventional counting mechanism which is capable of registering the number of fetal movements input by the user. The counter may be separate from the processor, or may be part of the processor itself. The device is preferably programmable so that the patient's doctor or clinician can chose which of several available "kick-count" protocols to utilize, as described hereinabove, depending upon the doctor's preference. For the illustrated embodiment, the device

1 is shown as utilizing the Moore and Piacquadio protocol, in which case the index
2 utilized is a simple value of ten movements within a two hour period. Thus, the
3 processor compares the number of movements input to the index and, for the present
4 embodiment, once ten movements are input within a two hour time period the
5 processor sends a signal that the session has been successfully completed. If,
6 however, ten movements are not input within a two hour time period the processor
7 sends a signal that the session has not been successfully completed and the indicator
8 notifies the user to this effect. The processor which is utilized in the device may be
9 any conventional processor, as would be known to one of skill in the art.

10 The device may further include a second and third input member 20, 22 in
11 order to set or change (increase or decrease) various parameters, such as the time, date
12 and/or estimated due date, or other parameters described in further detail hereinbelow.
13 In the present embodiment, input member 12 is preferably used to select the variable
14 which is being adjusted, such as the due date, while the second and third input
15 member 20, 22 are used to increase and decrease the value of each variable (Fig. 10).
16 The third input member 20 may also function to turn on a back light for visualizing
17 the LCD during the run mode and in low light environments. A toggle member 24
18 may also be provided to toggle between the available modes, for example the "run"
19 mode which the patient uses for counting fetal movement, and the "set" mode which
20 is used to program the various parameters such as time, date, due date, etc. All of the
21 input members may be in the form of button, or may take other forms as would be
22 known to one of skill in the art.

23 The device may be initially set by either the clinician or the patient, for
24 example by inputting the correct time and date. In either case, the user may also be
25 required to enter the estimated due date (EDD) once the current date and time are set.
26 The kick counter may then be programmed to begin functioning during the 28th week
27 of gestation until the 45th week of gestation is completed, after which time the device
28 can be programmed to disable itself so that the device will no longer function as a kick
29 counter. The kick counting device may also be turned off (for example in the "set"

-10-

1 mode) by either the patient or the clinician after the delivery of the baby. In addition,
2 the device may also be programmed to allow the patient/clinician to change the due
3 date only a certain amount of times, for example three, so that the user cannot extend
4 the use of the device beyond the 45th week of gestation. Once disabled for use in
5 counting fetal movement, the device may preferably still function as a conventional
6 watch.

7 Referring now to Fig. 2, the device also includes indicator or display 16 which
8 is preferably utilized to convey various forms of information to the user. In the
9 present embodiment, when utilized to count fetal movements the display preferably
10 includes the current number of fetal movements registered 26 and the elapsed time 28
11 since the beginning of the session. The display may also display the number of
12 sessions completed during the day, if an alternate protocol other than the Moore
13 Piacquadio protocol is utilized. The display can also display other information of
14 interest, such as the number of days left until the patient's due date 30 (or the days past
15 the due date), information concerning the fetus, for example when sexual organs
16 develop, and/or reminders to the patient, for example to practice breathing techniques
17 or Kegel exercises, if desired. The information of interest can be programmed into the
18 device to be displayed at appropriate times during the pregnancy, depending upon the
19 estimated due date (i.e. a pregnancy calender).

20 The display 16 may also provide various other prompts or signals to the user.
21 For example, the display may prompt the user to begin a session by displaying indicia,
22 such as the words "READY" or "BEGIN COUNT" (FIG. 1), may indicate the
23 successful completion of a session by display indicia, such as the word "OK" (Fig. 7),
24 may indicate the interruption of a session by displaying indicia, such as the word
25 "CANCEL" (Fig. 9), may display a warning to the user if the session is not
26 successfully completed (i.e. the 2 hour time limit is reached before the tenth
27 movement is counted, a.k.a. "movement alarm signal"), such as "ALARM"(Fig. 6) or
28 "CALL YOUR OB/GYN", and may also display a warning if the user has failed to
29 track fetal movements for a predetermined amount of time (for example 5 days), such

-11-

1 as "CALL YOUR OB/GYN" (Fig. 3) or "CALL YOUR DOC". The non-use warning
2 signal may additionally include some indication which differentiates non-use from the
3 movement alarm signal, such as a predetermined letter, e.g. "F", or a number. In the
4 case of either non-use or an unsuccessful session, the device may be programmed to
5 disable itself until reset either manually by the user or by the doctor or clinician. The
6 device may be reset, for example, by holding down a reset button, or by inputting a
7 code provided by the patient's doctor or clinician. Any of the above visual displays
8 may additionally be accompanied by an audible indication, such as a beep or buzz, or
9 may alternately be replaced by the audible indication. For example, the "ALARM"
10 indicia may be accompanied by an audible alarm in the form of two double beeps or
11 may be replaced by the audible alarm. The display may be a liquid crystal display
12 (LCD), LED, or similar display, as would be known to one of skill in the art.

13 In a preferred embodiment, the device 10 stores the previous day's results,
14 which can be easily accessed by the clinician or the patient. For example, the previous
15 day's results may be accessed by holding down the input member 12 between 12
16 midnight and 6 p.m., i.e. when the device is not being used as a fetal movement
17 counting device under the Moore and Piacquadio protocol (Fig. 5). Alternately, other
18 methods of accessing the previous day's or other previous results may be accessed by
19 known methods, such as by downloading the results to either a stand-alone base unit
20 or through a peripheral device connected to a personal computer. In either case, a
21 printout of the patient's results would be available for placement in the patient's
22 prenatal record. The fetal movement device can store up to about sixteen weeks of
23 patient's results (or as many weeks as appropriate). For the exemplary protocol, the
24 previously recorded results preferably include the date and the elapsed time to reach
25 the tenth movement or, if ten movements were not recorded, then the number of
26 movements recorded and the elapsed time.

27 When not functioning as a fetal movement counting device, the present device
28 may function as a standard watch. For example, as depicted in Fig. 10 the device may
29 display the date, time and any other pertinent information. The device may also take

-12-

1 any number of forms, including but not limited to a watch, necklace, electronic
2 personal organizer and may be carried in a woman's pocket, clipped on to clothing
3 (like a beeper) or worn on the woman's clothing or body. When utilized as part of a
4 personal organizer, the device may include any number of other option, such as an
5 address book, appointment calender, etc. as would be conventional with an electronic
6 personal organizer. The device may also be programmed, as described above, to
7 display other information of interest and/or reminders to the patient.

8 The present invention offers several advantages, which may make it a valuable
9 tool for both pregnant woman and their obstetricians. First, having a device
10 specifically designed for recording fetal movement acts as a reminder and provides
11 positive reinforcement for pregnant women who have been asked by their physicians
12 to record fetal activity. Second, by automating this technique, the pregnant woman
13 is automatically prompted to begin kick counting and receives automatic feedback,
14 such as notification of the successful or unsuccessful completion of a session. These
15 automated features are particularly useful to a pregnant woman who is often
16 preoccupied with other tasks and who may, therefore forget to initiate kick-counting.
17 In addition, there is no need for women to keep track of 1) the number of kicks
18 perceived, 2) the starting time, or 3) the ending time in confusing and complicated
19 charts. The electronic kick count recorder can also be used to provide a record of both
20 kick count results and alarm signals, which can be documented in the patient's chart.
21 Finally, women will most definitely appreciate the interest their obstetricians are
22 taking in their prenatal care by prescribing the kick count recorder. Use of the fetal
23 movement recording device will now be described with respect to the Moore and
24 Piacquadio protocol.

25 In the program based on the Moore and Piacquadio protocol, the device may
26 only function as a kick count recorder between 6:00 PM and 12:00 MN. At all other
27 times it may, if desired, display the time, date, day of week and days until the
28 estimated due date. At 6:00 PM, each night from the 28th week of gestation on, the
29 device will display "READY" and await input by the user (Figure 1). If no input is

-13-

1 entered by 7:00 PM, the device may double beep once every 30 minutes until 11:30
2 PM, or until input member 12 is pressed, which initiates the session. At any time
3 between 6:00 PM and 12:00 MN, the patient may begin her two hour session by
4 pressing input member 12, and the message "BEGIN COUNT" may appear. At this
5 point, the "ELAPSED TIME" is displayed in hours and minutes and the number of
6 recorded kicks is displayed on the display, for example in box 32 (Figure 2). The
7 present time and date may also be displayed as well in the upper portion 34 of the
8 display. The patient then presses the input member 12 each time she perceives a fetal
9 movement, i.e. any discrete kick, flutter, swish, or roll. If the tenth kick is recorded
10 within the upper time limit of two hours for the instant protocol, the results will be
11 displayed (the result mode); and the device will acknowledge the successful
12 completion of the session, for example by a visual indication such as "OK" (Fig. 7)
13 appearing on the display. After 10 seconds, the display may then revert to the current
14 time, date, and day of week, and the device will not be available for kick count
15 recording until the following day at 6:00 PM.

16 If the two hour time limit expires prior to recording the tenth kick, otherwise
17 defined as the movement alarm, the display may read "ALARM" (Fig. 6), and an
18 audible alarm may also sound (for example, a double beep for 10 seconds, then two
19 double beeps every 15 minutes) until the device has been reset, or the device may
20 disable itself until reset by the patient's care giver. Alternately, the patient may reset
21 the device by holding the input member 12 down for 4 seconds (the device may
22 double beep after each second). The device may also be programmed to signal the
23 user if other criteria which may indicate fetal compromise are met (e.g., a pattern of
24 increasing amount of elapsed time to reach ten movements).

25 If the patient interrupts her session (by pressing input member 12 for four
26 seconds - which may be accompanied by double beeps every second), the display will
27 read CANCEL (Fig. 9) for that day, unless the patient subsequently completes a valid
28 session later in the same day, between 6 p.m. and 12 midnight, in which case the latter
29 results will be displayed.

-14-

After 12:00 midnight, the device may again display the time, date, and day of week, but will not record kick counts. After five continuous days of non-use, the device may display a message such as "CALL YOUR OBGYN"/"CALL YOUR DOC" (Fig. 3), or other such phrase, and an audible alarm may sound, as described hereinabove. A predetermined letter (e.g., "F") or number may also appear in the box to differentiate this warning from a movement alarm signal. The patient may then reset the device as described herein above.

The steps of the present invention are further depicted in part in the following Tables 1 through 3. The present invention preferably includes three modes as described hereinabove, i.e. the run mode (Table 1) in which fetal movement is registered by the user, the results mode (Table 2) in which results from current/and or past sessions are displayed, and the set mode (Table 3) in which various parameters such as date and time are set and/or changed. As described above, toggle member 24 may be provided in order to shift between the various modes of the device.

In the run mode, the device may complete the steps enumerated in Table 1 below. The column labeled "function" indicates a particular function accomplished by the device, and the column labeled "display" indicates the reading on the display 16 at the time of the corresponding function. Table 1 is provided for illustrative purposes only, and is not intended to limit the scope of the invention as the steps enumerated in Table 1 may vary, as would be apparent to one of skill in the art.

Table 1: Run mode (Moore/Piacquadio protocol)

STEP	FUNCTION	DISPLAY
1	During the day, the device functions as a watch, displaying the time, date and day on the LCD.	11-29-97 WED A 11:22

-15-

2	At 6:00 PM, the device becomes available for kick counting.	6:00 PM READY
3	At 7:00 PM, if patient has not initiated session, device may double-beep. With continued non-use, the device may double-beep (once) every 30 minutes until 11:30 PM.	7:00 PM READY
4	If no entry by 12 MN, device goes back to watch function, and is unavailable for kick counting until the following evening at 6:00 PM.	11-30-97 WED A 12:01
5	If 5 days of continuous non-use, display may read...	CALL YOUR OBGYN
6	If during step 2 or 3, session initiated ... ("6:06 PM" may alternate with "START COUNT"). Buttons 20, 22 and 24 are preferably inactive during kick counting sessions.	6:06 PM 0:00 0 ELAPSED TIME
7	Here, four kicks have been recorded in 20 minutes.	6:26 PM 0:20 4 ELAPSED TIME
8	If 10 kicks recorded within 2:00 HR...device may double-beep four times to let patient know she does not need to record any more kicks. After 10 seconds, "OK" may be displayed and the device may then revert back to watch, until following day at 6:00 PM.	6:48 PM OK

9	After successful completion of kick counting session, display reverts back to watch functions.	11-29-97 WED P 6:48
10	If the patient decides to interrupt her session before counting 10 kicks (and before 2 hr), she may hold button 12 down for 4 seconds (accompanied by double-beeps every second). If the current time is still before 12:00 MN, the patient may initiate a new session for that same day. She may not initiate a session after 12:00 MN. This interruption may be recorded in the results (see Table 2 below).	11:07 PM READY
11	If, however, 2 hours pass before 10 kicks are recorded...(in this case, only 7 kicks were recorded during the 2 hour session).	8:06 PM 2:00 7 ELAPSED TIME
12	...a message appears (and the device may double-beep ten times - cannot be silenced) instructing the patient to call her clinician. Device may not function until it is reset. The number of kicks recorded during the session may remain in the display.	CALL YOUR OBGYN 7

-17-

13	The patient may reset the device herself by holding button 12 down for 4 seconds (accompanied by double-beeps every second) or it may be reset by her care provider. The "alarm" may be recorded, however, in the previous day's result. The device may function as a watch until the following day at 6:00 PM.	11-29-87 WED P 8:06
----	---	---------------------------

1 It should be noted that in step 2 of Table 1 a "Research Version" may be
2 available that will be available for kick counting at any time of day. In step 12 of table
3 1, a reminder double-beep every 30 minutes to 1 hour could follow the initial beeps.

4 Table 2 depicts the result mode of the present invention, which may, for
5 example, be accessed from run mode by pressing and holding the input button 12
6 depicted in Figure 1. The column labeled "function" indicates a particular function
7 accomplished by the device, and the column labeled "display" indicates the display at
8 the time of the corresponding function. Again, Table 2 is provided for illustrative
9 purposes only, and is not intended to limit the scope of the invention as the steps
10 enumerated in Table 2 may vary, as would be apparent to one of skill in the art

Table 2 Result mode

STEP	FUNCTION	DISPLAY
1	Previous day's results displayed (between the hours of 12 MN and 6 PM). The number of days left until the patient's due date may also be displayed. If the pregnancy progresses beyond the estimated due date, the display may read "days past" over the number in the box.	RESULT 11-22 DAYS LEFT 0:38 25
2	If movement alarm signal occurred (i.e., elapsed time greater than 2 hours) on the previous day, display may indicate an alarm occurred. For example, "ALARM" may flash and double-beep twice.	ALARM 11-17 DAYS LEFT 2:00 30
3	If no entry occurred on the previous day...	RESULT 11-18 DAYS LEFT -- : -- 29
4	If the patient interrupted a session, this message may appear ... or ...	RESULT 11-16 DAYS LEFT CANCEL 31

-19-

5	If the patient then completed a session on the same day...	RESULT 11-16 DAYS LEFT 0:52 31
6	Releasing input button 12 will return the display to the current time, day and date.	11-29-98 WED A 11:22

1 Table 3 depicts the set mode of the present invention, which may, for example,
2 be accessed from the run mode by pressing toggle button 24. In the set mode, all time
3 and date values can be adjusted by the patient. The column labeled "function"
4 indicates a particular function accomplished by the device, and the column labeled
5 "display" indicates the display at the time of the corresponding function. Table 3 is
6 also provided for illustrative purposes only, and is not intended to limit the scope of
7 the invention as the steps enumerated in Table 3 may vary, as would be apparent to
8 one of skill in the art.

Table 3 Set mode

STEP	FUNCTION	DISPLAY
1	Input button 12 may be used to select the variable (i.e., 11 → 30 → 97 → P → 12 → 27 → Y) which will blink, indicating that the value of the variable can be changed. Button 20 preferably increases and button 22 decreases the value of the variable. The letter in the box can toggle between Y (for yes) or N (for no), depending on whether the patient would like the daily kick counting function (and the number of days left) activated. This allows patients to turn the kick counting function off after delivery. If she does not turn off the kick counting function, kick counting will automatically shut off five weeks after her entered due date (after 45th week of gestation).	11-30-97 P 12:27 Y COUNT

2	<p>Upon completion of setting the above variables (for the first time only), pressing button 24 may then toggle to a new Set submode - the EDD (or estimated Date of Delivery). This date is determined by the clinician. Button 12 will again change the variable (i.e., MAR U 17 U 98) which will blink, indicating that the value of the variable can be changed. Button 20 again is used to increase and button 22 to decrease the value of the variable. Once set, this due date can preferably not be altered and will automatically begin 12 weeks before this due date (28th week of pregnancy) and will terminate automatically 5 weeks after the due date (45th week of pregnancy) if not shut off before this time. as described above.</p>	<p>MAR-17-98</p> <p>EDD</p>
3	<p>Alternatively, the due date can be altered (to make allowances for clinical changes made in the due date) by not more than 30 days - in either direction, earlier or later preferably not more than 2-3 times. This will be reflected in the months available to the patient in the set mode.</p>	

1 It will be understood that various modifications may be made to the
2 embodiment disclosed herein. For example, although described for use with the
3 Moore/Piacquadio protocol, the device may be programmed for use with any kick-

-22-

1 count protocol and the device may include visual displays an/or audible displays, for
2 example an audible beep to begin counting and a visual display to display the results
3 of the session. Also, although the device may function in a separate mode as a
4 personal organizer, watch, etc., it does not have to have a separate mode and may
5 simply function only as a device for monitoring fetal movement. Likewise, although
6 the device is preferably disabled after the 45th week or delivery of the baby, it does
7 not have to disable itself and may continue to function in its capacity as a kick counter.
8 In addition, although several different modes for providing information to the user are
9 illustrated, only the alarm mode need be included in the device. Therefore, the above
10 description should not be construed as limiting, but merely as exemplifications of a
11 preferred embodiment. Those skilled in the art will envision other modifications
12 within the scope spirit of the invention.

CLAIMS

- 1 1. A device for fetal monitoring, comprising:
2 an input member actuatable by a user to input perceived fetal movements into
3 the device;
4 a timer for timing a session during which the user inputs perceived fetal
5 movements;
6 a processor programmed to compare the inputted perceived fetal movements
7 relative to an index in order to determine if a desired target result has been achieved;
8 an indicator configured and arranged to inform the user if the desired target
9 result has not been achieved.
- 1 2. The device according to claim 1, wherein the processor is programmed to
2 automatically prompt the user to begin inputting perceived fetal movements.
- 1 3. The device according to claim 2, wherein the prompt is an audible prompt.
- 1 4. The device according to claim 1, wherein the indicator is a visual display.
- 1 5. The device according to claim 1, wherein the indicator further operates to
2 inform the user if the desired target result has been achieved.
- 1 6. The device according to claim 1, wherein the indicator further operates to
2 inform the user if the session has been interrupted.
- 1 7. The device according to claim 1, wherein the indicator further operates to
2 inform the user if no perceived fetal movement has been input for a predetermined
3 amount of time.

-24-

1 8. The device according to claim 1, wherein the indicator further operates to
2 inform the user of the results of current and past sessions.

1 9. The device according to claim 1, wherein the indicator further operates to
2 inform the user of the current time when not being utilized by the user to input
3 perceived fetal movements.

1 10. The device according to claim 1, further including a counter constructed and
2 arranged to register perceived fetal movements input by the user.

1 11. The device according to claim 10, wherein the counter is part of the processor.

1 12. The device according to claim 1, wherein the device is constructed and
2 arranged to be worn by the user.

1 13. The device according to claim 1, wherein the device is constructed and
2 arranged as part of a personal organizer.

1 14. The device according to claim 1, further comprising a toggle member to toggle
2 between various available modes of the device.

1 15. A method of fetal monitoring, comprising the steps of:
2 providing a device including an input member actuatable by a user to input
3 perceived fetal movements into the device;
4 comparing the inputted perceived fetal movements relative to an index in order
5 to determine if a desired target result has been achieved;
6 informing the user if the desired target result has not been achieved.

-25-

1 16. The method of claim 15, further comprising the step of prompting the user to
2 begin inputting perceived fetal movements into the device.

1 17. The method of claim 15, further comprising the step of informing the user if
2 the desired target result has been achieved.

1 18. The method of claim 15, further comprising the steps of informing the user if
2 the session has been interrupted and informing the user if no perceived fetal
3 movement has been input for a predetermined amount of time.

1 19. The method of claim 15, further comprising the step of displaying the results
2 of past sessions.

1 20. A device for fetal monitoring, comprising:
2 an input member actuatable by a user to input perceived fetal movements into
3 the device;
4 a timer for timing a session during which the user inputs perceived fetal
5 movements;
6 a processor programmed to prompt the user to begin counting fetal movement
7 and to compare the inputted perceived fetal movements relative to an index in order
8 to determine if a desired target result has been achieved;
9 an indicator configured and arranged to inform the user if the desired target
 result has or has not been achieved.

1/7

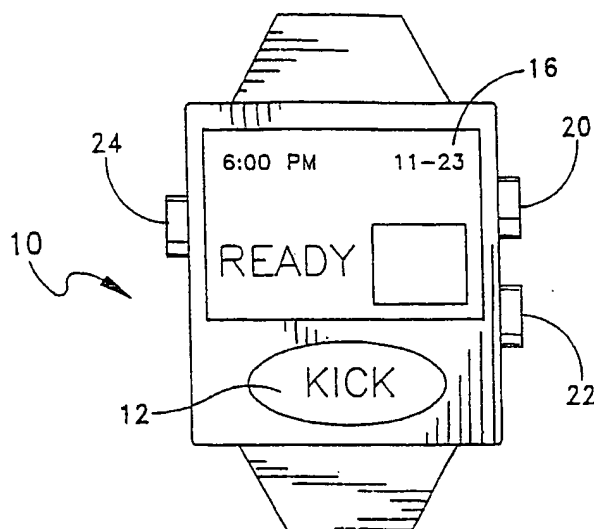


FIG. 1

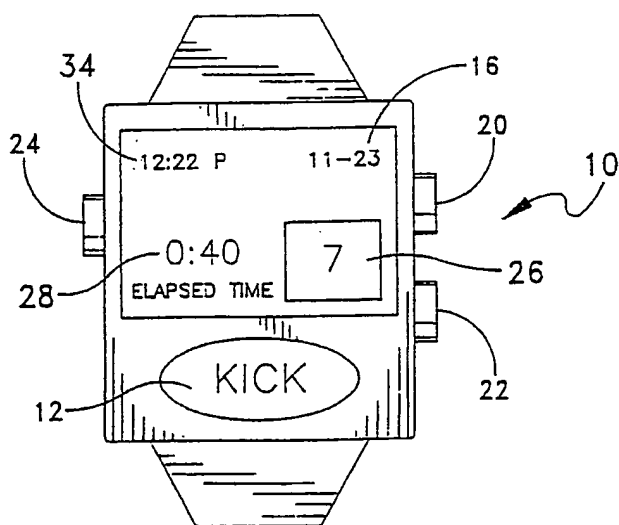


FIG. 2

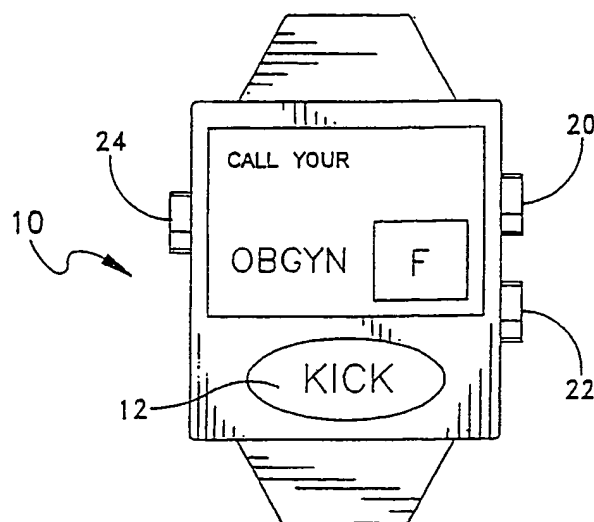


FIG. 3

2/7

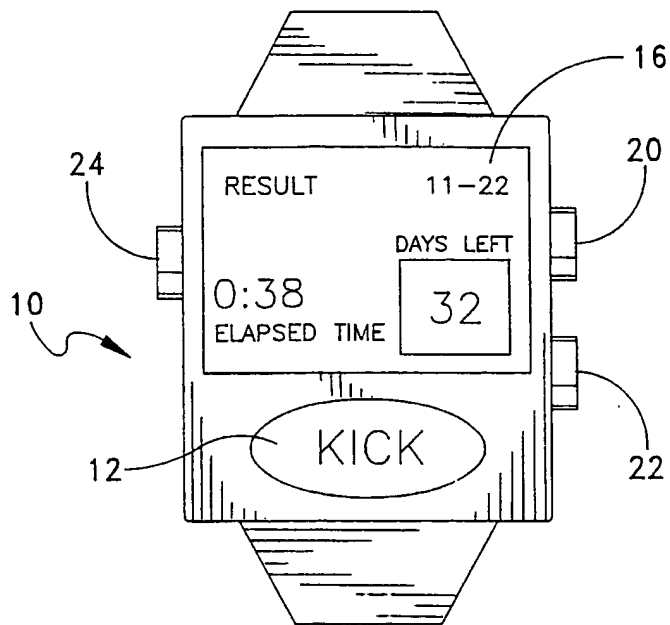


FIG. 4

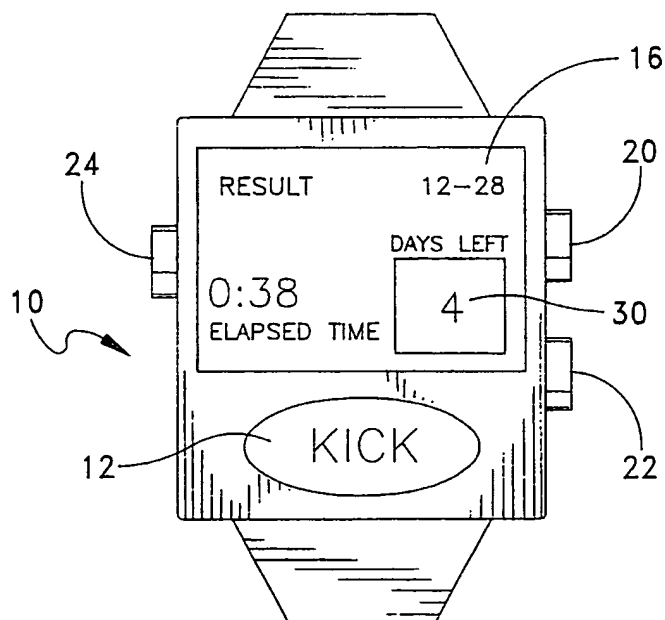


FIG. 5

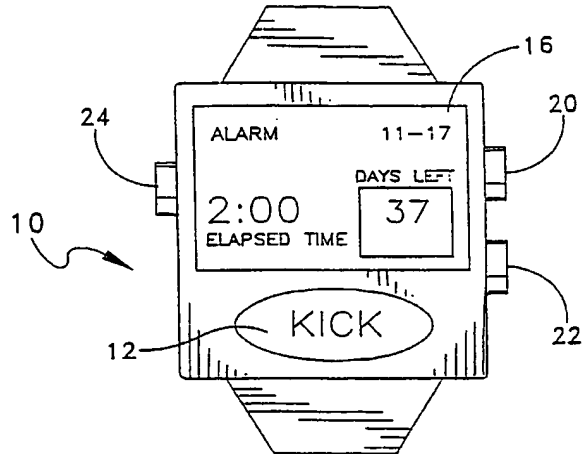


FIG. 6

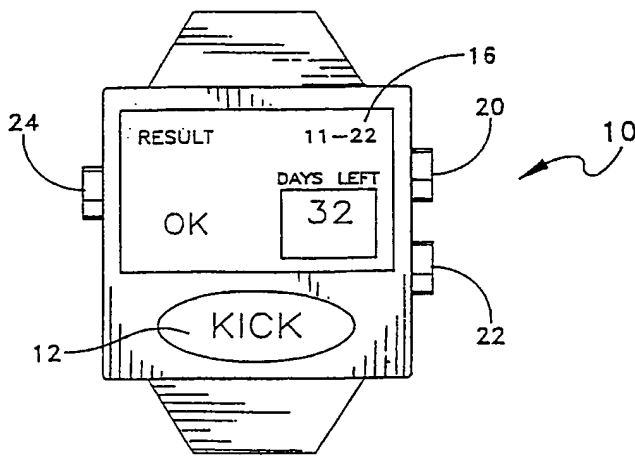


FIG. 7

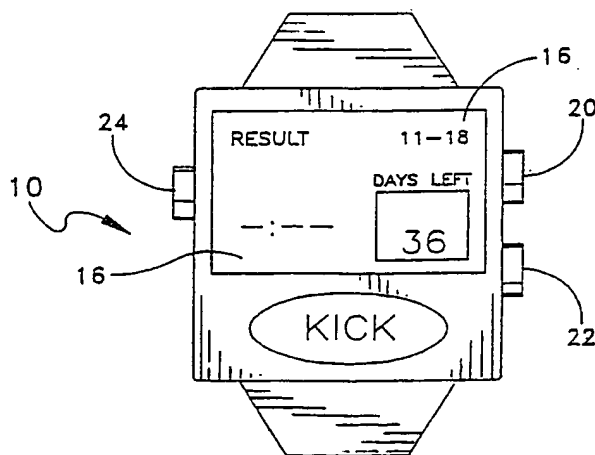


FIG. 8

4/7

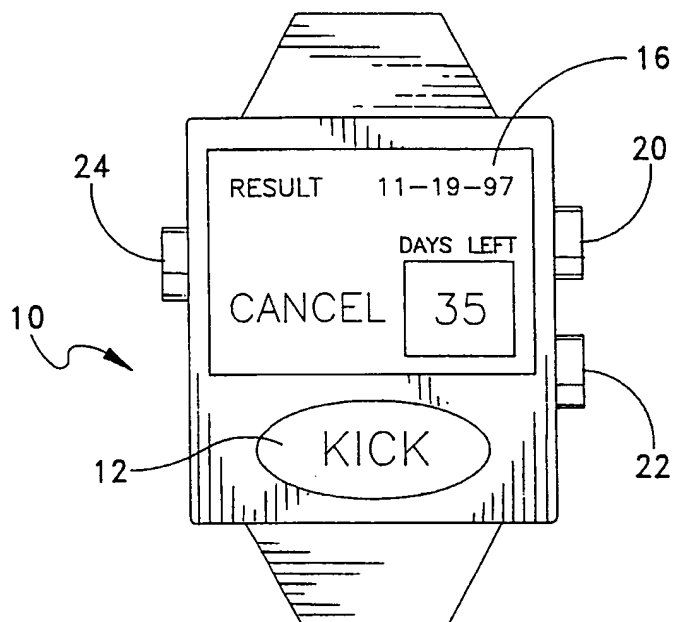


FIG. 9

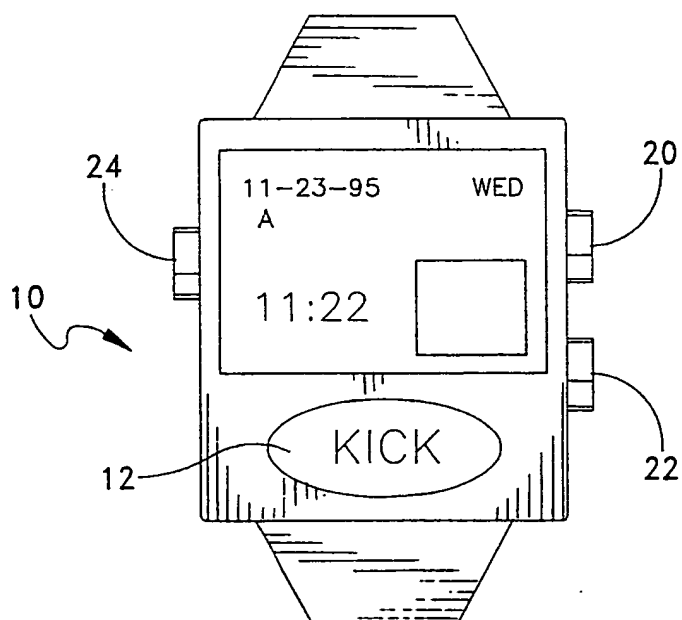


FIG. 10

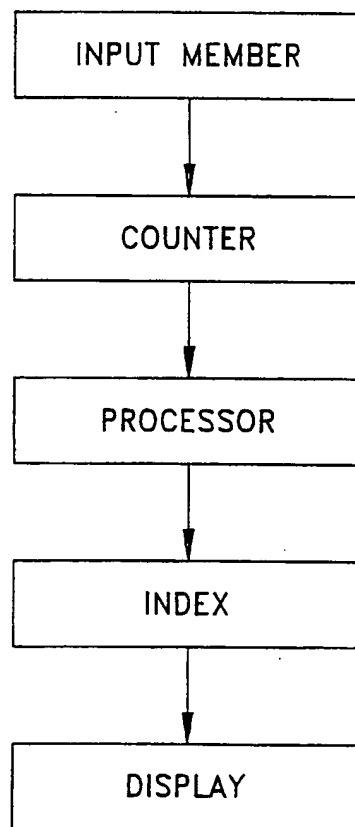


FIG. 11

6/7

FIG. 12A

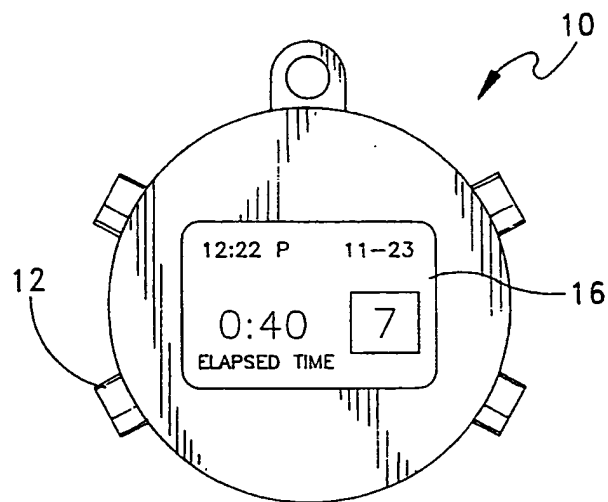
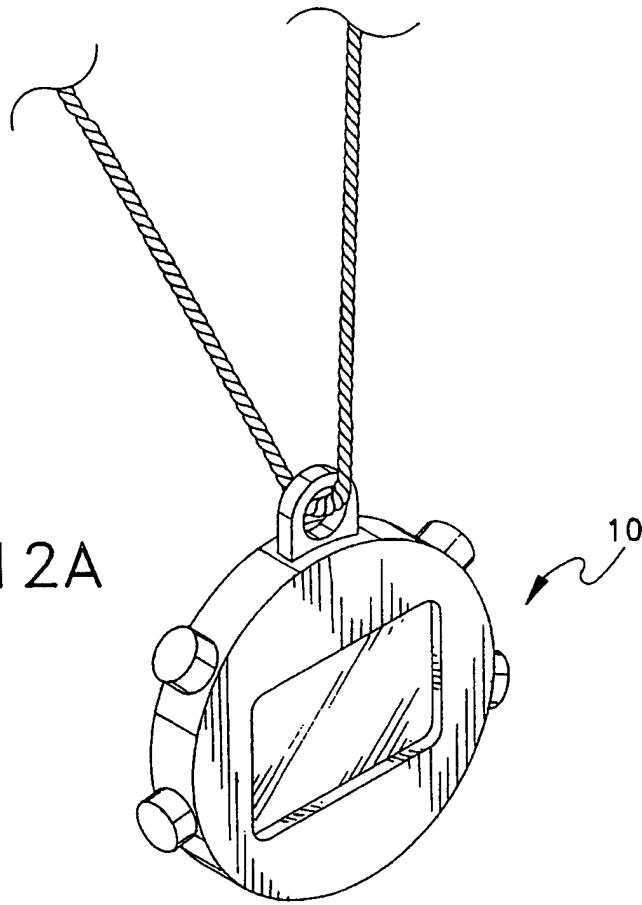


FIG. 12B

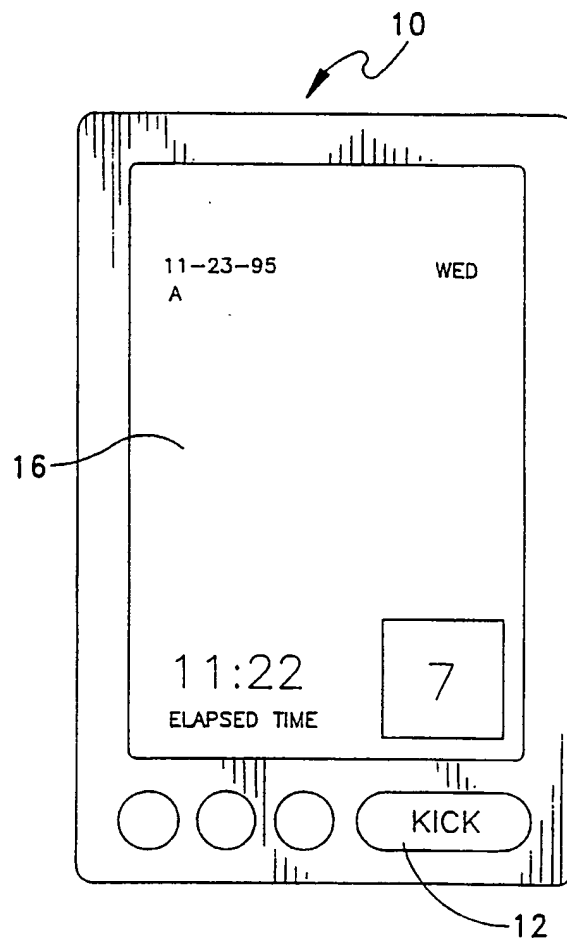


FIG. 13

INTERNATIONAL SEARCH REPORT

Int. .tional Application No

PCT/US 99/07426

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G04F10/00 G04G1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 G04G A61B G04F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 193 015 A (RUSTON JOSEPH HENRY;BARBUR JOHN LAZAR) 27 January 1988 (1988-01-27)	1-12, 14-20
Y	page 1, column 5 - page 2, column 56 ---	13
Y	US 4 493 043 A (FORBATH FRANK P) 8 January 1985 (1985-01-08) column 15, line 9 - column 17, line 39 ---	13
A	WO 89 04140 A (RUSTON JOSEPH HENRY ;BARBUR JOHN LAZAR (GB)) 18 May 1989 (1989-05-18) page 4, line 1 - page 9, last paragraph ---	1-20
P,X	US 5 876 335 A (HANDY JEFFREY D ET AL) 2 March 1999 (1999-03-02) figures 1-29 -----	1-20

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

9 July 1999

Date of mailing of the international search report

16/07/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Exelmans, U

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/07426

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2193015 A	27-01-1988	WO 8904140 A	18-05-1989
US 4493043 A	08-01-1985	AT 40483 T	15-02-1989
		AU 564303 B	06-08-1987
		AU 1045483 A	17-06-1983
		EP 0094962 A	30-11-1983
		WO 8302015 A	09-06-1983
WO 8904140 A	18-05-1989	GB 2193015 A	27-01-1988
US 5876335 A	02-03-1999	NONE	